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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,909	12/24/2003	Malcolm Wilson Moon	034536-0920	9163
22428	7590	12/23/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			ANDERSON, REBECCA L	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,909

Applicant(s)

MOON ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-53 is/are pending in the application.
- 4a) Of the above claim(s) 47-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-46 is/are rejected.
- 7) ☒ Claim(s) 37-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

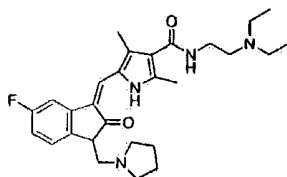
- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/24/03, 6/29/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claims 37-53 are currently pending in the instant application. Claims 47-53 are withdrawn from consideration as being for non-elected inventions. Claims 37-46 are objected to as containing non-elected subject matter and are rejected.

Election/Restrictions

Applicant's election with traverse of Group I, claims 37-46 and the further election of the compound:



in the reply filed on 24 September 2004 is acknowledged. The traversal is on the ground(s) that the search and examination on the merits should proceed in accordance with MPEP 803.02. This is not found persuasive because the restriction requirement is made under 35 USC 121. 35 USC 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. So, here we have claims which involve more than one independent and distinct invention. Under 35 USC 121,

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the claims may be restricted and the examination limited to a restricted invention.

Therefore, as stated on page 3 of the restriction requirement, upon the election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound and examination will then proceed on the elected compound and the scope of the determined independent invention encompassing the elected compound.

The elected invention for search and examination is the products of the formula (I) wherein:

R3, R5, R6, R7, R4, R1', R8, R10 and R9 are as found in claim 37 and

R3' and R4' together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.

The remaining subject matter of claims 37-46 that is not drawn to the above elected invention and the subject matter of claims 47-53 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining compounds which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are, for example wherein R3' and R4' are lower alkyl optionally substituted hydroxy or R3' and R4' together with the nitrogen atom to which they are attached, form 2-(S)-hydroxymethylpyrrolidin-1-yl, 2-(S)-carboxy-pyrrolidin-1-yl, piperazin-1-yl, 4-methylpiperazin-1-yl, pyrro-1-yl, pyridin-1-yl, oxazol-3-yl, isoxazol-2-yl, pyrazin-1-yl, pyradizin-1-yl, quinolin-1-yl and imidazol-1-yl, etc.

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The above mentioned withdrawn compounds which are withdrawn from consideration as being for nonelected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds differ from those of the elected invention, such as by pyridine, piperazine, oxazolyl, imidazolyl, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 544 subclass (358)+ piperazine, class 548 subclass (215)+ oxazolyl, class 548 subclass (356.1)+ imidazolyl, etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefor withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

Specification

The abstract of the disclosure is objected to because the table on page 88 is not numbered. If this table is a continuation of Table 1 on page 87, the page should be amended to state this. If this is a separate table, the page should be amended to state "Table II, " and the table on page 89 should be amended to state "Table III." Also, the paragraph starting on line 7 of page 89 is objected to because of the statement, "any

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clones, DNA or amino acid sequences which are functionally equivalent are within the scope of the invention." Since the specification does not discuss any clones, DNA or amino acid sequences, it is impossible to have any functional equivalents. This statement should be omitted. This paragraph is also objected to because of the reference to accompanying drawings. There were no drawings received with this application, therefore, this reference should be omitted. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 37-46 are objected to as containing non-elected subject matter. Claims 37-46 presented drawn solely to the elected invention identified supra and free from the following double patenting rejections would appear allowable over the prior art of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

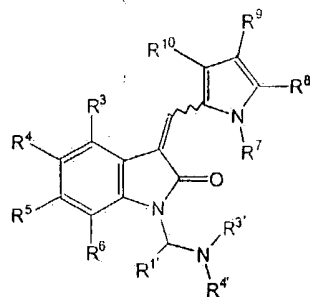
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37-42 and 46 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6451838. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected invention of Applicants instant claims 37-42 and 46 are drawn to pharmaceutical compositions and compounds of the formula (I):



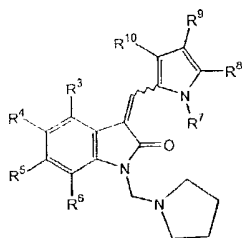
(I).

Wherein R³, R⁵ and R⁶ are for example, hydrogen, alkyl, trihaloalkyl, etc; R⁷ is hydrogen, R⁴ is hydrogen or halo, R^{1'} is hydrogen or methyl, R⁸ and R¹⁰ are independently unsubstituted lower alkyl, R⁹ is hydrogen, lower alkyl substituted with C-carboxy or =C(=O)NHR¹³, R¹³ is lower alkyl substituted with amino or heteroalicyclic, R^{3'} and R^{4'}, together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.

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The conflicting claims 1-9 of US Patent No. 6451838 claims compounds of the formula

(I):



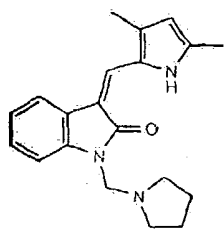
(I)

wherein the position equivalent to applicants R1' is hydrogen; the position equivalent to applicants R3' and R4' together with the nitrogen atom to which they are attached is an unsubstituted pyrrolidin-1-yl; conflicting R3, R4, R5 and R6 are for example, hydrogen, alkyl, trihaloalkyl, halo, etc.; conflicting R7 is, for example hydrogen and alkyl; and conflicting R8, R9 and R10 are for example, hydrogen, alkyl (conflicting claim 1).

Conflicting claim 2 provided preferences to applicants instantly claimed compounds since conflicting claim 2 claims the compound of formula (I) wherein R7 is hydrogen.

Conflicting claim 3 provides preferences towards applicants instantly claimed compounds since conflicting claim 3 claims the compound of formula (I) wherein R3, R4, R5, R6, R7 and R9 are hydrogen and R8 and R10 are unsubstitued lower alkyl.

Conflicting claim 5, which discloses the compound:



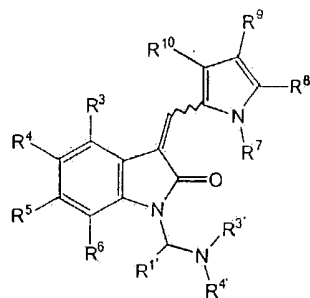
is fully encompassed by applicants instant claims 37-42 and therefor anticipates applicants instantly claimed invention. Conflicting claim 7, which is a pharmaceutical

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composition of the compound of conflicting claim 5 is fully encompassed by applicants instant claim 46 and therefore anticipated applicants instantly claimed invention.

Therefore, claims 37-42 and 46 are rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over conflicting claims 1-9 of US Patent No. 6451838 since the conflicting claims overlap with applicants instantly claimed invention, provide preferences towards applicants instantly claimed invention and provide (see conflicting claims 5 and 7) compounds and pharmaceutical compositions which are completely encompassed by applicants instantly claimed invention and therefore anticipate applicants instantly claimed invention.

Claims 37-43 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6710067. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected invention of Applicants instant claims 37-43 and 46 are drawn to pharmaceutical compositions and compounds of the formula (I):



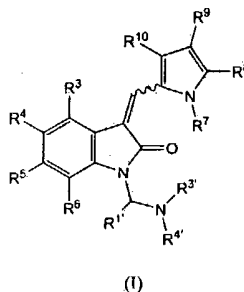
(I).

Wherein R³, R⁵ and R⁶ are for example, hydrogen, alkyl, trihaloalkyl, etc; R⁷ is hydrogen, R⁴ is hydrogen or halo, R^{1'} is hydrogen or methyl, R⁸ and R¹⁰ are independently unsubstituted lower alkyl, R⁹ is hydrogen, lower alkyl substituted with C-

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carboxy or $=C(=O)NHR_{13}$, R_{13} is lower alkyl substituted with amino or heteroalicyclic, $R_{3'}$ and $R_{4'}$, together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.

Conflicting claims 1-9 of US Patent No. 6710067 claim the pharmaceutical compositions and compounds of the formula (I)



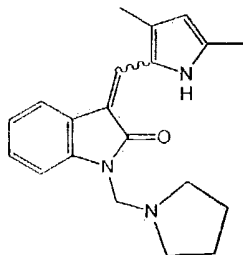
wherein the position equivalent to applicants $R_{1'}$ is hydrogen or alkyl; the position equivalent to applicants $R_{3'}$ and $R_{4'}$ together with the nitrogen atom to which they are attached is an unsubstituted pyrrolidin-1-yl; conflicting R_3 , R_4 , R_5 and R_6 are for example, hydrogen, alkyl, trihaloalkyl, halo, etc.; conflicting R_7 is, for example hydrogen and alkyl; and conflicting R_8 , R_9 and R_{10} are for example, hydrogen, alkyl (conflicting claim 1). Conflicting claim 2 provided preferences to applicants instantly claimed compounds since conflicting claim 2 claims the compound of formula (I) wherein $R_{1'}$ and R_7 are hydrogen. Conflicting claims 2 and its dependent conflicting claims 3 and 4 provide preferences towards applicants instantly claimed compounds since conflicting claim 3 claims the compound of formula (I) wherein $R_{1'}$ and R_7 are hydrogen, R_3 , R_4 , R_5 , R_6 , and R_9 are hydrogen and R_8 and R_{10} are unsubstituted lower alkyl and conflicting claim 4 claims R_8 and R_{10} as methyl and therefore claims 3 and 4 anticipate applicants instantly claimed invention since the claimed compounds of conflicting claims 3 and 4 are fully encompassed by applicants instant claimed invention. Conflicting

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claims 6 and 7 provide a preference to R9 as lower alkyl substituted with carboxy.

Conflicting claims 8 and 9 are pharmaceutical compositions claims comprising the compounds of the formula (I). Therefore, claims 37-43 and 46 are rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over conflicting claims 1-9 of US Patent No. 671--67 since the conflicting claims overlap with applicants instantly claimed invention, provide preferences towards applicants instantly claimed invention and provide (see conflicting claims 3 and 4) compounds which are completely encompassed by applicants instantly claimed invention and therefore anticipate applicants instantly claimed invention.

Claim 46 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 18, 19, 36, 38 and 39 of copending Application No. 10/300930. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claims 18, 19, 36, 38 and 39 are specific pharmaceutical formulations, which anticipate applicants instantly claimed pharmaceutical composition of claim 46 which comprises a pharmaceutically acceptable carrier or excipient and the compound of claim 37. Conflicting claims 16, 18, 19, 36, 38 and 39 disclose the pharmaceutical formulations comprising the compound:

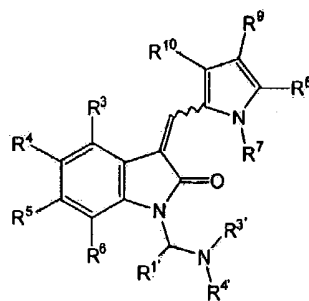


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and pharmaceutically acceptable complexing agents or surfactant, acceptable acids, antioxidants, water and/or acceptable buffers, which are completely encompassed by applicants instant claim 46 and therefore claim 46 is provisionally rejected as being unpatentable over conflicting claims 18, 19, 36, 38 and 39 of copending Application No. 10/300930.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 37-41 and 43-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-25 and 27-30 of copending Application No. 10/429895. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected invention of Applicants instant claims 37-41 and 46 are drawn to pharmaceutical compositions and compounds of the formula (I):



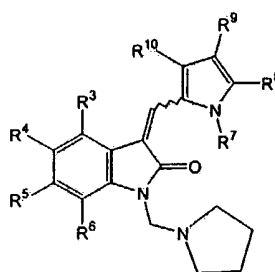
(I)

Wherein R³, R⁵ and R⁶ are for example, hydrogen, alkyl, trihaloalkyl, etc; R⁷ is hydrogen, R⁴ is hydrogen or halo, R^{1'} is hydrogen or methyl, R⁸ and R¹⁰ are independently unsubstituted lower alkyl, R⁹ is hydrogen, lower alkyl substituted with C-carboxy or =C(=O)NHR¹³, R¹³ is lower alkyl substituted with amino or heteroalicyclic,

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R3' and R4', together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.

Conflicting claims 22-25, 27, 28, 29 and 30 are claiming pharmaceutical compositions and compounds of the formula (I)



(I)

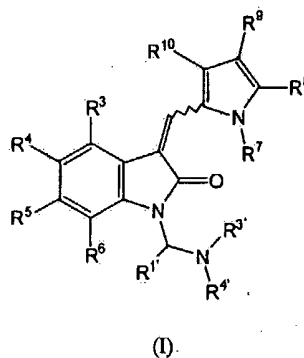
Wherein R3, R5 and R6 can be for example, hydrogen, alkyl, trihaloalkyl, etc; R7 is hydrogen, the position equivalent to applicants instant R1' is hydrogen, the position equivalent to applicants R3' and R4' along with the nitrogen to which they are attached is unsubstituted pyrrolidin-1-yl; R7 is hydrogen, R8 and R10 are unsubstituted lower alkyl and R9 is lower alkyl substituted with C-carboxy, or $-C(=O)NHR_{13}$ and pharmaceutical compositions which are fully encompassed by applicants instantly claimed elected invention and therefore anticipate applicants instantly claimed elected invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 37-41 and 43-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 60-62, 65, 66, 74-48 and 97-99 of copending Application No. 10/774415. Although the conflicting claims are not identical, they are not patentably distinct from each other

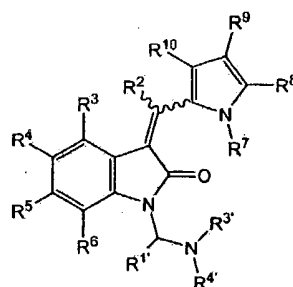
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because Claims 37-41 and 43-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-25 and 27-30 of copending Application No. 10/429895. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected invention of Applicants instant claims 37-41 and 46 are drawn to pharmaceutical compositions and compounds of the formula (I):



Wherein R3, R5 and R6 are for example, hydrogen, alkyl, trihaloalkyl, etc; R7 is hydrogen, R4 is hydrogen or halo, R1' is hydrogen or methyl, R8 and R10 are independently unsubstituted lower alkyl, R9 is hydrogen, lower alkyl substituted with C-carboxy or =C(=O)NHR13, R13 is lower alkyl substituted with amino or heteroalicyclic, R3' and R4', together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.

Conflicting claims 60-62, 65, 66, 74-78 and 97-99 claim pharmaceutical compositions and compounds of the formula (II)



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Wherein R2 is hydrogen, R3, R4, R5, and R6 are for example, hydrogen, alkyl, trihaloalkyl, halo; R7 is for example, hydrogen or alkyl, R8 and R10 are unsubstituted lower alkyl, R1' is hydrogen or alkyl (conflicting claim 60), R9 is preferably (2-diethylaminoethyl)aminocarbonyl or (2-ethylaminoethyl)-aminocarbonyl (conflicting claims 61 and 62); R3' and R4' preferably form a pyrrolidin-1-yl (conflicting claims 65 and 66). Conflicting claims 74-77 provide preferences towards applicants instantly claimed invention since R1', R3, R5, R6 and R7 are hydrogen, R4 is halo, R8 and R10 are unsubstituted lower alkyl, R9 can be (2-diethylaminoethyl)aminocarbonyl (conflicting claims 75 and 76 and R3' and R4' form a pyrrolidin-1-yl group (conflicting claim 77). Furthermore, conflicting claim 78 claims, for example, a compound (3Z)-3-[[3,5-dimethyl-4-(2-diethylaminoethylaminocarbonyl)-1H-pyrrol-2-yl]-methylidene]-1-(1-pyrrolidinylmethyl)-1,3-dihydro-2H-indol-2-one which provides further preference towards applicants instantly claimed compound. Claims 97-99 are pharmaceutical composition claims. Therefore, claims 37-41 and 43-46 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over conflicting claims 60-62, 65, 66, 74-78 and 97-99 since the conflicting claims overlap with applicants instantly claimed invention, provide preferences towards applicants instantly claimed invention and provide the compound (3Z)-3-[[3,5-dimethyl-4-(2-diethylaminoethylaminocarbonyl)-1H-pyrrol-2-yl]-methylidene]-1-(1-pyrrolidinylmethyl)-1,3-dihydro-2H-indol-2-one which is completely encompassed by applicants instantly claimed invention.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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